K042084

JUN 15 2005

**510(k) summary as described in § 807.92**

**510(k) Summary**

Submitter: **BioDerm Sciences, Inc.**
Enterprise Center
9 Industrial Park Drive, Suite 1N
Oxford, Mississippi 38655
Phone: (301) 216-3912

Contact Person: Ed Gubish Ph. D. <egubish@biodermsciences.com>
Chief Scientific Officer

Preparation Date: May 26, 2005

Proprietary Device Name: BioDerm Wound Spray

Classification Name: Liquid Bandage

Predicate Devices:

| | |
|---|---|
| BioDerm Wound Solution | K040683 |
| Dermagran wound cleanser with zinc | K945802 |
| Restore Wound Cleanser | K040779 |

Description:

BioDerm Wound Spray is an acidic zinc-saline wet dressing for external wound management. It aids the body in the healing process by providing a moist, acidic wound environment. The non-irritating components of BioDerm Wound Spray allow it to be used in the mouth, eyes and on mucous membranes as well as on the skin.

BioDerm Wound Spray is similar in chemical composition to the previously cleared BioDerm Sciences Wound Solution with the spray also containing 0.002% of some trace elements. A difference between these products is that the predicate device BioDerm Sciences Wound Solution is supplied sterile in injection bottles, while the current device is supplied non-sterile in pump-spray bottles. The dressing is applied by spraying onto the affected area.

BioDerm Wound Spray is supplied in 100 ml spray bottles with a plunger activated pump applicator.

Intended Use (Prescription):

BioDerm Sciences Wound Spray is intended to cleanse, rinse and externally manage dermal lesions such as lacerations, post-operative (surgical) wounds, partial

and full-thickness wounds, burns and ulcers (diabetic, venous stasis, pressure). It is meant to be used in conjunction with a sterile dressing that absorbs fluids (i.e. gauze, gel, alginate, foam, hydrocolloid).

Intended Use (OTC): BioDerm Sciences Wound Spray is intended to clean, rinse and externally manage skin wounds such as minor lacerations, minor cuts, minor burns and abrasions.

BioDerm Wound Spray can also be used as a wound cleanser to remove foreign matter, bacteria and tissue debris.

BioDerm Wound Spray is contraindicated for use when patients are known to have had allergic reactions to this dressing or its components. It is not suitable for use on third degree burns, or for any wound for which the dermis has been severely damaged or is missing.

Comparison of Technological Characteristics:

A number of wet dressings have been cleared for marketing by the FDA. All have in common that they are saline solutions based on sodium chloride or metallic salts with a pH less than or equal to 7 (i.e. acidic). They may or may not contain additives such as nutrients. BioDerm Wound Spray is supplied non-sterile.

A broad range of chemical compositions is currently available. The chemical composition of BioDerm Wound Spray is within the range of chemical compositions of these predicate devices and is substantially equivalent in terms of its safety and effectiveness. (See Table 1)

Performance:

A study of various formulations with varying strength levels of the metallic salts, performed at the University of Miami (Department of Dermatology & Cutaneous Surgery) using a porcine model demonstrated the effectiveness of BioDerm Wound Spray as an aid to the body's healing of burns, and partial wounds.

Conclusions:

When used as directed, BioDerm Wound Spray is safe and effective as a wound cleanser or wet dressing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2007

Edward R. Gubish, Ph.D.
Chief Scientific Officer
BioDerm Sciences Inc.
Enterprise Center
9 Industrial Park Drive, Suite 1N
Oxford, Mississippi 38665

Re: K042084
Trade Name: BioDerm Sciences Wound Spray
Regulatory Class: Unclassified
Product Code: FRO
Dated: May 17, 2005
Received: May 18, 2005

Dear Dr. Gubish:

This letter corrects our substantially equivalent letter of June 15, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

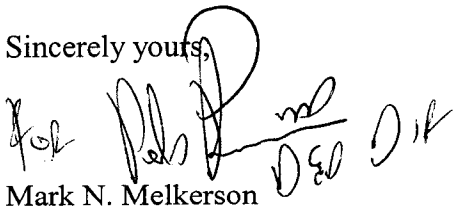
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K042084

**Indications for Use**

510(k) Number: TBD

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Prescription Use__X___
(Part 21 CFR 801 Subpart D)

Over-the-Counter Use_____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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